IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, Defendants.	Civil Action No. 1:18-88 (LPS) CONSOLIDATED PUBLIC VERSION FILED JULY 5, 2019

HETERO USA, INC., HETERO LABS LIMITED, AND HETERO LABS LIMITED UNIT-V'S ANSWER AFFIRMATIVE DEFENSES TO FIRST AMENDED COMPLAINT AND COUNTERCLAIMS

Defendants Hetero USA, Inc. ("Hetero USA"), Hetero Labs Limited ("Hetero Labs"), and Hetero Labs Limited Unit-V ("Hetero Unit V") (collectively "Hetero" or "Defendants") respond to the numbered paragraphs of the First Amended Complaint filed April 18, 2019, by Plaintiffs H. Lundbeck A/S ("Lundbeck") and Takeda Pharmaceutical Company Ltd., Takeda Pharmaceutical U.S.A., Inc., Takeda Pharmaceutical International AG, and Takeda Pharmaceutical America, Inc. (collectively, "Takeda") (Lundbeck and Takeda, collectively, "Plaintiffs") as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiffs' First Amended Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. Hetero admits that this action purports to be an action for patent infringement against Hetero in relation to Abbreviated New Drug Application ("ANDA") No. 210987, which seeks approval to market vortioxetine hydrobromide tablets prior to the expiration of U.S. Patent

Nos. 8,722,684 ("the '684 Patent"); 8,969,355 ("the '355 Patent"); 9,227,946 ("the '946 Patent"); and 9,861,630 (the '630 Patent). Hetero denies the remaining allegations of paragraph 1.

THE PARTIES

2. Paragraph 2 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits only that Lundbeck was identified as the assignee on the face of the '684, '355, '946,'630, '910, and '096 patents. Hetero is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 2, and therefore denies them.

3. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

5. Paragraph 5 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits only that the electronic version of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") currently lists "Takeda USA" as the apparent holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX®. Hetero is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 5, and therefore denies them.

6. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 6, and therefore denies them.

7. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7, and therefore denies those allegations.

8. Hetero admits only that Hetero USA is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1035 Centennial Avenue, Piscataway, NJ, 08854. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 8.

9. Hetero admits the allegations in Paragraph 9.

10. Hetero admits the allegations in Paragraph 10.

11. Hetero denies the allegations in Paragraph 11.

12. Paragraph 12 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that Hetero USA has been designated as the U.S. agent for Hetero Labs and Hetero Unit V with respect to certain of its ANDA filings. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 12.

13. Hetero denies the allegations in Paragraph 13.

14. Paragraph 14 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 14.

15. Hetero admits the allegations in Paragraph 15.

16. Hetero admits the allegations in Paragraph 16.

17. Paragraph 17 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine

hydrobromide tablets as described in ANDA No. 210987 (the "Hetero ANDA Products"). Hetero denies any remaining allegations or legal conclusions contained in Paragraph 17.

18. Hetero denies the allegations in Paragraph 18.

19. Paragraph 19 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as described in ANDA No. 210987 (the "Hetero ANDA Products").

20. Paragraph 20 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as described in ANDA No. 210987 (the "Hetero ANDA Products").

JURISDICTION AND VENUE

21. Paragraph 21 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that the Complaint purports to be a civil action that arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '684, '355, '946,'630, '910, and '096 Patents. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 21.

22. Paragraph 22 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero does not contest that subject matter jurisdiction is proper in this judicial district pursuant to 28 U.S.C. §§ 1331 and 1338. Hetero denies the remaining allegations of Paragraph 22.

23. Paragraph 23 of the Amended Complaint contains legal conclusions to which no response is required. Although Hetero does not admit that personal jurisdiction in this individual

district is proper as to all defendants, Hetero waives its objection to personal jurisdiction for the purposes of this action only. Hetero denies the remaining allegations of paragraph 23.

24. Hetero admits the allegations in Paragraph 24.

25. Hetero admits that it is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, in the United States. Hetero denies any other allegations contained in Paragraph 25.

26. Hetero admits the allegations in Paragraph 26.

27. Hetero admits that it sent letters dated December 18, 2017 and January 26, 2018 to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) (the "First Notice Letter" and the "Second Notice Letter" or collectively, the "Notice Letters") which speak for themselves. Hetero denies the remaining allegations of Paragraph 27.

28. Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 28 since they relate to speculative future events, and therefore, denies them.

29. Paragraph 29 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 29 since they relate to speculative future events, and therefore denies them.

30. Paragraph 30 of the Complaint contains allegations and/or legal conclusions to which no response is required. The documents filed in the civil actions identified in Paragraph 30 of the Complaint speak for themselves, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 30.

31. Paragraph 31 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it has waived its objection to personal jurisdiction for the purposes of this action only.

32. Defendants admit that Hetero USA is a corporation organized and existing under the laws of the State of Delaware. Although Hetero does not admit that venue in this context proper with respect to all defendants, Hetero waives any objection to venue for the purposes of this action only. Hetero denies all other allegations contained in Paragraph 32.

33. Defendants admit that Hetero Labs is a corporation organized and existing under the laws of the Republic of India. Although Hetero does not admit that venue in this context is proper with respect to all defendants, Hetero waives any objection to venue for the purposes of this action only. Hetero denies all other allegations contained in Paragraph 33.

34. Paragraph 34 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it has waived its objection to personal jurisdiction for the purposes of this action only.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

35. Hetero admits that the electronic version of the Orange Book currently lists "Takeda USA" as the holder of NDA No. 204447, approved on September 30, 2013, for TRINTELLIX® (active ingredient vortioxetine hydrobromide) tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Hetero denies all other allegations in Paragraph 35.

36. Paragraph 36 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits that the "Indications and Usage" section for the labeling for TRINTELLIX® tablets (for oral use), approved April 11, 2017, states that TRINTELLIX® is "indicated for the treatment of major

depressive disorder (MDD)." Hetero also admits that the "Clinical Pharmacology" section of the labeling for TRINTELLIX®, approved April 11, 2017, states that "[t]he mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT)" and that "[v]ortioxetine binds to 5-HT3 (Ki=3.7 nM), 5-HT1A (Ki=15 nM), 5-HT7 (Ki=19 nM), 5-HT1D (Ki=54 nM), and 5-HT1B (Ki=33 nM), receptors and is a 5-HT3, 5-HT1D, and 5-HT7 receptor antagonist, 5-HT1B receptor partial agonist, and 5-HT1A receptor agonist." Hetero is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 32, and therefore denies them.

37. Paragraph 37 of the Complaint contains legal conclusions which require no response. To the extent a response is required Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 37, and therefore denies them.

38. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 38, and therefore denies them.

39. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 39, and therefore denies them.

40. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 40, and therefore denies them.

41. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 41, and therefore denies them.

42. Hetero is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 42, and therefore denies them.

43. Hetero admits that the ’684, ’355, ’946, and ’630, ’910, and ’096 Patents are listed in the Orange Book for NDA No. 204447, which relates to TRINTELLIX®. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 43.

44. Hetero admits that the ’684 Patent indicates an issue date of May 13, 2014, and is entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Hetero admits that Exhibit A of the Complaint purports to be a copy of the ’684 patent. Hetero denies the remaining allegations of Paragraph 44.

45. Hetero admits that the ’355 Patent indicates an issue date of March 3, 2015, and is entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Hetero admits that Exhibit B of the Complaint purports to be a copy of the ’355 patent. Hetero denies the remaining allegations of Paragraph 45.

46. Hetero admits that the ’946 Patent indicates an issue date of January 5, 2016, and is entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Hetero admits that Exhibit C of the Complaint purports to be a copy of the ’946 patent. Hetero denies the remaining allegations of Paragraph 46.

47. Hetero admits that the ’630 Patent indicates an issue date of January 9, 2018, and is entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Hetero admits that Exhibit D of the Complaint purports to be a copy of the ’630 patent. Hetero denies the remaining allegations of Paragraph 47.

48. Hetero admits that the ’910 Patent indicates an issue date of September 8, 2015, and is entitled “1-[2-(2,4 dimethylphenylsulfanyl)-phenyl]piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Hetero admits that Exhibit E of the Complaint purports to be a copy of the ’910 patent. Hetero denies the remaining allegations of Paragraph 48

49. Hetero admits that the ’096 Patent indicates an issue date of March 8, 2016, and is entitled “Therapeutic Uses of Compound Having Combined SERT, 5-HT3 and 5-HT1A Activity.” Hetero admits that Exhibit F of the Complaint purports to be a copy of the ’096 patent. Hetero denies the remaining allegations of Paragraph 49.

DEFENDANTS’ ANDA NO. 210987

50. Hetero admits that ANDA No. 210987 was submitted to the FDA under 21 U.S.C. § 355(j), contains certifications under 21 U.S.C. §355(j)(2)(A)(vii)(IV) (“Paragraph IV Certifications”) as to the ’684, ’355, ’946, and ’630 Patents, and seeks approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets prior to the expiration of the ’684, ’355, ’946, and ’630, ’910, and ’096 Patents. Hetero denies any remaining allegations of Paragraph 50.

51. Paragraph 51 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as described in ANDA No. 210987 (the “Hetero ANDA Products”).

52. Paragraph 52 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it

seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as described in ANDA No. 210987 (the "Hetero ANDA Products").

53. Hetero admits the allegations in Paragraph 53.

54. Paragraph 54 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Hetero USA sent a First Notice Letter dated December 18, 2017 notifying Lundbeck, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals that ANDA No. 210987 had been submitted and contained Paragraph IV Certifications with respect to the '684, '355, and '946 Patents. Hetero denies the remaining allegations of Paragraph 54.

55. Paragraph 55 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Hetero USA sent a Second Notice Letter dated January 26, 2018 notifying Lundbeck, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals that a Paragraph IV Certification had been made with respect to the '630 Patent in connection with ANDA No. 210987. Hetero denies the remaining allegations of Paragraph 55.

56. Paragraph 56 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it submitted ANDA No. 210987 to the FDA under § 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, or sale of at least one of the products described in ANDA No. 210987 before the expiration of the '684, '355, '946, '630, '910, and '096 Patents. Hetero denies any other allegations contained in Paragraph 56.

57. Paragraph 57 of the Complaint contains legal conclusions which require no response. Hetero admits that the Notice Letters offered Plaintiffs access to portions of ANDA

No. 210987 under terms and conditions set forth in the Notice Letters, which speak for themselves. Hetero denies any other allegations contained in Paragraph 57.

58. Paragraph 58 of the Complaint contains legal conclusions which require no response. Hetero admits that counsel for Hetero and outside counsel for Plaintiffs corresponded regarding the offer for confidential access provided in the Notice Letters, and that Hetero transmitted its ANDA to Plaintiffs on July 25, 2018. Hetero denies any other allegations contained in Paragraph 58.

59. Paragraph 59 of the Complaint contains legal conclusions which require no response. To the extent a response is required, Hetero admits that pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), the Notice Letters enclosed a detailed statement of the legal and factual bases for its Paragraph IV Certifications that in Hetero's opinion, and to the best of its knowledge, the '684, '355, '946, and '630 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Hetero's ANDA No. 210987. The requirements for the regulations promulgated by the FDA, including 21 C.F.R. §§ 314.95(c)(7) and 314.52, speak for themselves. Hetero denies any other allegations contained in Paragraph 59.

60. Paragraph 60 of the Complaint contains legal conclusions and/or allegations which require no response. To the extent a response is required, the Notice Letter speaks for itself and is the best source for its contents, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such contents. Hetero denies any other allegations contained in Paragraph 60.

61. Paragraph 61 of the Complaint contains legal conclusions and/or allegations which require no response. To the extent a response is required, Hetero admits only that ANDA

No. 210987 includes proposed labeling which speaks for itself, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such labeling. Hetero denies any other allegations contained in Paragraph 61.

62. Paragraph 62 of the Complaint contains legal conclusions which require no response. To the extent a response is required, Hetero is presently without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 62 since they relate to speculative future events, and therefore denies them.

63. Paragraph 63 of the Complaint contains legal conclusions which require no response. To the extent a response is required, Hetero is presently without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 63 since they relate to speculative future events, and therefore denies them.

64. Paragraph 64 of the Complaint contains legal conclusions which require no response. To the extent a response is required, Defendants admit that Hetero USA sent a First Notice Letter dated December 18, 2017 notifying Lundbeck, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals that ANDA No. 210987 had been submitted and contained Paragraph IV Certifications with respect to the ’684, ’355, and ’946 Patents. Defendants further admit that Hetero USA sent a Second Notice Letter dated January 26, 2018 notifying Lundbeck, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals that a Paragraph IV Certification had been made with respect to the ’630 Patent in connection with ANDA No. 210987. Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 64, and therefore denies them.

65. Paragraph 65 of the Complaint contains legal conclusions which require no response. To the extent a response is required Hetero admits that it has not submitted a

Paragraph III certification for the ’910 and ’096 Patents and that it has submitted a Paragraph IV certification in connection with ANDA No. 210987 for other patents listed in the Orange Book for Trintellix®. Hetero denies the remaining allegations of Paragraph 65.

COUNT I
ALLEGED INFRINGEMENT OF THE ’684 PATENT

66. Hetero repeats and incorporates its responses to Paragraphs 1-65 as if fully set forth herein.

67. Paragraph 67 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 67.

68. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 68, and therefore denies them.

69. Paragraph 69 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero refers to the stipulation filed at D.I. 117.

70. Paragraph 70 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, the Notice Letters speak for themselves and are the best source for their contents, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such contents. Hetero specifically denies that it is required by applicable regulations to state the basis for any and all invalidity or unenforceability positions it may have a basis to assert in this action in its Notice Letters. The requirements for the regulations promulgated by the FDA, including 21 C.F.R. §§ 314.95(c)(7) and 314.52, speak for themselves. Hetero denies any remaining allegations in Paragraph 70.

71. Paragraph 71 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 71.

72. Paragraph 72 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 72.

73. Paragraph 73 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 73.

74. Paragraph 74 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '684 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 74.

75. Paragraph 75 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero refers to the stipulation filed at D.I. 117.

76. Paragraph 76 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '684 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 76.

77. Paragraph 77 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 77.

78. Paragraph 78 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 78.

COUNT II
ALLEGED INFRINGEMENT OF THE '355 PATENT

79. Hetero repeats and incorporates its responses to Paragraphs 1-78 as if fully set forth herein.

80. Paragraph 80 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it

submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 80.

81. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 81, and therefore denies them.

82. Paragraph 82 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in paragraph 82 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '355 Patent.

83. Paragraph 83 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits only that ANDA No. 210987 includes an FDA-required proposed labeling for the Hetero ANDA Products and that proposed labeling speaks for itself, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such labeling. Hetero denies any remaining allegations of Paragraph 83.

84. Paragraph 84 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, the Notice Letters speak for themselves and are the best source for their contents, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such contents. Hetero specifically denies that it is required by applicable regulations to state the basis for any and all invalidity or unenforceability positions it may have a basis to assert in this action in its Notice Letters. The requirements for the regulations promulgated by the FDA, including 21 C.F.R. §§ 314.95(c)(7) and 314.52, speak for themselves. Hetero denies any remaining allegations in Paragraph 84.

85. Paragraph 85 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 85.

86. Paragraph 86 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 86.

87. Paragraph 87 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 87.

88. Paragraph 88 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '355 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 88.

89. Paragraph 89 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero refers to the stipulation filed at D.I. 117.

90. Paragraph 90 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '355 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 90.

91. Paragraph 91 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 91.

92. Paragraph 92 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 92.

COUNT III
ALLEGED INFRINGEMENT OF THE '946 PATENT

93. Hetero repeats and incorporates its responses to Paragraphs 1-92 as if fully set forth herein.

94. Paragraph 94 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it

submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 94.

95. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 95, and therefore denies them.

96. Paragraph 96 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 79 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '946 Patent.

97. Paragraph 97 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits only that ANDA No. 210987 includes an FDA-required proposed labeling for the Hetero ANDA Products and that proposed labeling speaks for itself, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such labeling. Hetero denies any remaining allegations of Paragraph 97.

98. Paragraph 98 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, the Notice Letters speak for themselves and are the best source for their contents, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such contents. Hetero specifically denies that it is required by applicable regulations to state the basis for any and all invalidity or unenforceability positions it may have a basis to assert in this action in its Notice Letters. The requirements for the regulations promulgated by the FDA, including 21 C.F.R. §§ 314.95(c)(7) and 314.52, speak for themselves. Hetero denies any remaining allegations in Paragraph 98.

99. Paragraph 99 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 99.

100. Paragraph 100 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 100.

101. Paragraph 101 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 101.

102. Paragraph 102 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '946 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 102.

103. Paragraph 103 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero refers to the stipulation filed at D.I. 117.

104. Paragraph 104 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '946 Patent prior to filing ANDA No. 210987. Hetero denies all other allegations in Paragraph 104.

105. Paragraph 105 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 105.

106. Paragraph 106 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 106.

COUNT IV
ALLEGED INFRINGEMENT OF THE '630 PATENT

107. Hetero repeats and incorporates its responses to Paragraphs 1-106 as if fully set forth herein.

108. Paragraph 108 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it

submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 108.

109. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 109, and therefore denies them.

110. Paragraph 110 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 110 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '630 Patent.

111. Paragraph 111 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits only that ANDA No. 210987 includes an FDA-required proposed labeling for the Hetero ANDA Products and that proposed labeling speaks for itself, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such labeling. Hetero denies any remaining allegations of Paragraph 111.

112. Paragraph 112 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, the Notice Letters speak for themselves and are the best source for their contents, and Hetero denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such contents. Hetero specifically denies that it is required by applicable regulations to state the basis for any and all invalidity or unenforceability positions it may have a basis to assert in this action in its Notice Letters. The requirements for the regulations promulgated by the FDA, including 21 C.F.R. §§ 314.95(c)(7) and 314.52, speak for themselves. Hetero denies any remaining allegations in Paragraph 112.

113. Paragraph 113 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 113.

114. Paragraph 114 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 114.

115. Paragraph 115 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 115.

116. Paragraph 116 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '630 Patent prior to mailing the Notice Letter dated January 26, 2018. Hetero denies all other allegations in Paragraph 116.

117. Paragraph 117 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero refers to the stipulation filed at D.I. 117.

118. Paragraph 118 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it was aware of the '630 Patent prior to mailing the Notice Letter dated January 26, 2018. Hetero denies all other allegations in Paragraph 118.

119. Paragraph 119 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 119.

120. Paragraph 120 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 120.

COUNT V
ALLEGED INFRINGEMENT OF THE '910 PATENT

121. Hetero repeats and incorporates its responses to Paragraphs 1-120 as if fully set forth herein.

122. Paragraph 122 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 122.

123. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 123, and therefore denies them.

124. Paragraph 124 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 124 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

125. Paragraph 125 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 125 since they relate to speculative future events, and therefore, denies them.

126. Paragraph 126 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 126 since they relate to speculative future events, and therefore, denies them.

127. Paragraph 127 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, Hetero admits only that it seeks FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine

hydrobromide tablets as described in ANDA No. 210987 (the "Hetero ANDA Products"). Hetero denies any remaining allegations or legal conclusions contained in Paragraph 127.

128. Paragraph 128 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations on Paragraph 128.

129. Paragraph 129 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 129 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

130. Paragraph 130 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 130 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

131. Paragraph 131 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 131.

132. Paragraph 132 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 132 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '910 PATENT

133. Hetero repeats and incorporates its responses to Paragraphs 1-132 as if fully set forth herein.

134. Paragraph 134 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that the Complaint

purports to assert claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 134.

135. Paragraph 135 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 135.

136. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 136, and therefore denies them.

137. Paragraph 137 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 137 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

138. Paragraph 138 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 138 since they relate to speculative future events, and therefore, denies them.

139. Paragraph 139 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 139 since they relate to speculative future events, and therefore, denies them.

140. Paragraph 140 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it

submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 140.

141. Paragraph 141 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 141 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

142. Paragraph 142 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 142 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

143. Paragraph 143 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 143 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

144. Paragraph 144 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 144 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

145. Paragraph 145 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 145.

146. Paragraph 146 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 146

and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '910 patent.

COUNT VII
INFRINGEMENT OF THE '096 PATENT

147. Hetero repeats and incorporates its responses to Paragraphs 1-146 as if fully set forth herein.

148. Paragraph 148 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 148.

149. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 149, and therefore denies them.

150. Paragraph 150 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 150 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '096 patent.

151. Paragraph 151 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 151 since they relate to speculative future events, and therefore, denies them.

152. Paragraph 152 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or

information sufficient to form a belief as to the allegations set forth in Paragraph 152 since they relate to speculative future events, and therefore, denies them.

153. Paragraph 153 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 153.

154. Paragraph 154 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 154 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

155. Paragraph 154 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 154 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

156. Paragraph 156 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 156 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

157. Paragraph 157 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 157.

158. Paragraph 158 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 158 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '096 patent.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '096 PATENT

159. Hetero repeats and incorporates its responses to Paragraphs 1-159 as if fully set forth herein.

160. Paragraph 160 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that the Complaint purports to assert claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 160.

161. Paragraph 161 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 161.

162. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 162, and therefore denies them.

163. Paragraph 163 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 163 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the '096 patent.

164. Paragraph 164 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 164 since they relate to speculative future events, and therefore, denies them.

165. Paragraph 165 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 165 since they relate to speculative future events, and therefore, denies them.

166. Paragraph 166 of the Complaint contains legal conclusions and/or allegations to which no response is required. To the extent a response is required, Hetero admits that it submitted ANDA No. 210987 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of the Hetero ANDA Products. Hetero denies any remaining allegations contained in Paragraph 166.

167. Paragraph 167 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 167 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

168. Paragraph 168 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 168 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

169. Paragraph 169 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in

Paragraph 169 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

170. Paragraph 170 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 170 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

171. Paragraph 171 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 171.

172. Paragraph 172 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Hetero denies the allegations in Paragraph 172 and specifically denies that any Hetero ANDA Product would infringe any valid claim of the ’096 patent.

GENERAL DENIAL AND RESPONSE TO REQUEST FOR RELIEF

Any allegations in the Complaint not expressly admitted by Hetero are denied. Hetero denies that Plaintiffs are entitled to any judgment or relief requested in Paragraphs (A) through of their “Request for Relief.”

AFFIRMATIVE DEFENSES

Hetero asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hetero does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Hetero reserves the right to assert other defenses and/or

to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY OF THE '910 PATENT)

The claims of the '910 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(NONINFRINGEMENT OF THE '910 PATENT)

The manufacture, use offer for sale, sale, or importation of the products described in ANDA No. 210987 do not and will not infringe, directly or indirectly, any valid and enforceable claim of the '910 patent.

THIRD AFFIRMATIVE DEFENSE
(INVALIDITY OF THE '096 PATENT)

The claims of the '096 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(NONINFRINGEMENT OF THE '096 PATENT)

The manufacture, use offer for sale, sale, or importation of the products described in ANDA No. 210987 do not and will not infringe, directly or indirectly, any valid and enforceable claim of the '096 patent.

FIFTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Hetero reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

HETERO'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants Hetero Labs, Limited ("Hetero Labs"), Hetero USA, Inc. ("Hetero USA"), and Hetero Labs Limited Unit-V ("Hetero Unit V") (collectively, "Hetero"), for their Counterclaims against Plaintiffs/Counterclaim Defendants H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively "Plaintiffs"), allege as follows:

THE PARTIES

1. Hetero USA is a corporation organized under the laws of the state of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

2. Hetero Labs is a corporation organized and existing under the laws of India, and has its principal place of business in India at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

3. Hetero Unit V is a division of Hetero Labs and is located at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

4. Upon information and belief, Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

5. Upon information and belief, Takeda Japan is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuo-kuo, Osaka 540-8645, Japan.

6. Upon information and belief, Takeda International is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland. Upon further information and belief, Takeda International is an indirect wholly owned subsidiary of Takeda Japan.

7. Upon information and belief, Takeda USA is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Upon further information and belief, Takeda International and Takeda Japan own Takeda USA.

8. Upon information and belief, Takeda America is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Upon further information and belief, Takeda America is a wholly owned subsidiary of Takeda USA.

JURISDICTION

9. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

10. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(f) and 35 U.S.C. § 271(e)(5)).

11. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Hetero and Plaintiffs arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

12. This Court has personal jurisdiction over Plaintiffs based, *inter alia*, on the filing by Plaintiffs of this lawsuit in this jurisdiction and because Plaintiffs are doing business in this jurisdiction.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), and by Plaintiffs' choice of forum.

BACKGROUND

14. This is an action based on an actual controversy between the parties concerning the invalidity of United States Patent Nos. 8,722,684 ("the '684 patent"), 8,969,355 ("the '355 patent"), 9,227,946 ("the '946 patent"), 9,861,630 ("the '630 patent"), 9,125,910 ("the '910 patent"), and 9,278,096 ("the '096 patent") (collectively, "the Patents-in-Suit") and the noninfringement of the '910 and '096 patents; Hetero's right to continue to seek approval of ANDA No. 210987 seeking approval to engage in the commercial manufacture, use, or sale of the vortioxetine hydrobromide products described therein ("Hetero's ANDA Product"); and the right of Hetero to sell, market, distribute, or otherwise commercialize the product described in ANDA No. 210987.

15. Hetero has submitted ANDA No. 210987 to the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, importation, use, or sale of vortioxetine hydrobromide 5 mg, 10 mg, and 20 mg tablets.

16. The patents-in-suit are listed in the FDA's Approved Drugs Products with Therapeutic Equivalence Evaluations ("Orange Book") for the drug Trintellix®.

17. Upon information and believe, and based on Plaintiffs' allegations, Plaintiff Takeda USA is the holder of New Drug Application No. 204447 for Trintellix® containing the active ingredient vortioxetine hydrobromide.

18. Upon information and belief, Plaintiffs caused the patents-in-suit to be listed in the Orange Book in association with Trintellix®.

19. As a consequence of listing the patents-in-suit in the Orange Book, Plaintiffs were and are representing to the world that the patents-in-suit cover Trintellix® and vortioxetine hydrobromide, and that patent infringement actions relating to the patents-in-suit could reasonable be expected to be brought against unlicensed filers of ANDAs for which patent certification would be required.

20. Hetero certified to FDA in its ANDA No. 210987 that, in its opinion and to the best of its knowledge, its proposed vortioxetine hydrobromide product will not infringe any valid, enforceable claims of the '684, '355, '946, and '630 patents (collectively "the Original Patents-in-Suit").

21. As of the date of this filing, Hetero has not provided any certification to FDA in its ANDA No. 210987 regarding the '910 and '096 patents.

22. Hetero notified Plaintiffs of the factual and legal bases for its certification with respect to the Original Patents-in-Suit in letters on or about December 18, 2017 and January 26, 2018.

23. The Notification Letters included an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

24. Plaintiffs have filed in the Court an infringement action against Hetero to enforce the Patents-in-Suit.

25. In the Amended Complaint, Plaintiffs allege that Hetero has committed an act of infringement under 35 U.S.C. § 271(e) by filing ANDA No. 210987 seeking FDA approval to sell generic version of Trintellix® in the United States prior to the expiration of the Patents-in-Suit.

26. In the Amended Complaint, Plaintiffs also allege that Hetero will contribute to and/or induce infringement of the Patents-in-Suit by others.

27. Hetero has denied infringement of the ’910 and ’096 patents.

28. Hetero has further asserted that all Patents-in-Suit are invalid for failure to satisfy the provisions of one or more of Section 101, 102, 103, and/or 112 of Title 35 of the United States Code.

29. In view of the foregoing, a conflict of asserted rights has arisen between Hetero and Plaintiffs with respect to the noninfringement of the relevant claims of the ’910 and ’096 patents and the invalidity of the relevant claims of all Patents-in-Suit, with respect to Hetero’s right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of the products described in ANDA No. 210987. An actual controversy therefore exists between Hetero and Plaintiffs.

COUNT I
Declaratory Judgment of Invalidity of the ’684 Patent

30. Hetero realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

31. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’684 patent.

32. The asserted claims of the ’684 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, including that one or more of the claims of the ’684 patent is invalid under 35 U.S.C. § 102, 103, and/or 112 as anticipated and/or obvious in view of the disclosures in the prior art in the Notice Letter and Defendants’ Joint Initial Invalidity Contentions, served on November 16, 2018, which is incorporated by reference as though fully set forth herein.

33. Hetero is entitled to a judicial declaration that the claims of the ’684 patent are invalid.

COUNT II
Declaratory Judgment of Invalidity of the ’355 Patent

34. Hetero realleges and incorporates by reference the allegations of paragraphs 1-33 as though fully set forth herein.

35. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’355 patent.

36. The asserted claims of the ’355 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, including that

one or more of the claims of the ’684 patent is invalid under 35 U.S.C. § 102, 103, and/or 112 as anticipated and/or obvious in view of the disclosures in the prior art in the Notice Letter and Defendants’ Joint Initial Invalidity Contentions, served on November 16, 2018, which is incorporated by reference as though fully set forth herein.

37. Hetero is entitled to a judicial declaration that the claims of the ’355 patent are invalid.

COUNT III
Declaratory Judgment of Invalidity of the ’946 Patent

38. Hetero realleges and incorporates by reference the allegations of paragraphs 1-37 as though fully set forth herein.

39. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’946 patent.

40. The asserted claims of the ’946 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, including that one or more of the claims of the ’684 patent is invalid under 35 U.S.C. § 102, 103, and/or 112 as anticipated and/or obvious in view of the disclosures in the prior art in the Notice Letter and Defendants’ Joint Initial Invalidity Contentions, served on November 16, 2018, which is incorporated by reference as though fully set forth herein.

41. Hetero is entitled to a judicial declaration that the claims of the ’946 patent are invalid.

COUNT IV
Declaratory Judgment of Invalidity of the ’630 Patent

42. Hetero realleges and incorporates by reference the allegations of paragraphs 1-41 as though fully set forth herein.

43. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’630 patent.

44. The asserted claims of the ’684 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, including that one or more of the claims of the ’630 patent is invalid under 35 U.S.C. § 102, 103, and/or 112 as anticipated and/or obvious in view of the disclosures in the prior art in the Notice Letter and Defendants’ Joint Initial Invalidity Contentions, served on November 16, 2018, which is incorporated by reference as though fully set forth herein.

45. Hetero is entitled to a judicial declaration that the claims of the ’630 patent are invalid.

COUNT V
Declaratory Judgment of Invalidity of the ’910 Patent

46. Hetero realleges and incorporates by reference the allegations of paragraphs 1-45 as though fully set forth herein.

47. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’910 patent.

48. The asserted claims of the ’910 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation.

49. Hetero is entitled to a judicial declaration that the claims of the ’910 patent are invalid.

COUNT VI
Declaratory Judgment of Noninfringement of the ’910 Patent

50. Hetero realleges and incorporates by reference the allegations of paragraphs 1-49 as though fully set forth herein.

51. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the noninfringement of the asserted claims of the ’910 patent.

52. The manufacture, use, offer for sale, sale, importation, and/or marketing in the United States of Hetero’s ANDA Product would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of the ’910 patent either literally or under the doctrine of equivalents.

COUNT VII
Declaratory Judgment of Invalidity of the ’096 Patent

53. Hetero realleges and incorporates by reference the allegations of paragraphs 1-52 as though fully set forth herein.

54. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the invalidity of the asserted claims of the ’096 patent.

55. The asserted claims of the ’096 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation.

56. Hetero is entitled to a judicial declaration that the claims of the ’096 patent are invalid.

COUNT VIII
Declaratory Judgment of Noninfringement of the ’096 Patent

57. Hetero realleges and incorporates by reference the allegations of paragraphs 1-56 as though fully set forth herein.

58. There is an actual, substantial, and continuing case or controversy between Hetero and Plaintiffs regarding, *inter alia*, the noninfringement of the asserted claims of the ’096 patent.

59. The manufacture, use, offer for sale, sale, importation, and/or marketing in the United States of Hetero’s ANDA Product would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of the ’096 patent either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Hetero respectfully requests that this Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Hetero’s ANDA Product has not infringed, does not infringe, and would not–if made, used, sold, offered for sale, imported, or marketed–infringe, either directly or indirectly, any valid, enforceable claim of the ’910 and ’096 patents, either literally or under the doctrine of equivalents;

(b) Declaring that the asserted claims of the patents-in-suit are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112;

(c) Ordering that Plaintiffs’/Counterclaim Defendants’ Complaint be dismissed, with prejudice, and judgment entered in favor of Hetero;

(d) Declaring this case exceptional and awarding Hetero their reasonable attorneys' fees and costs under 35 U.S.C. § 285;

(e) Ordering that Plaintiffs/Counterclaim Defendants, and their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with them, be preliminarily and permanently enjoined from using the patents-in-suit to block, hamper, hinder, or obstruct FDA approval of the products described in Hetero's ANDA; and

(f) Awarding such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ John M. Seaman

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